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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,252	01/26/2004	Paul Price	0942.4120006/RWE/FRC	8017
26111	7590	04/18/2005	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			COE, SUSAN D	
			ART UNIT	PAPER NUMBER
			1654	
DATE MAILED: 04/18/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/763,252	Applicant(s) PRICE ET AL.	
	Examiner Susan D. Coe	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 14-17 and 22-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-13, 18-21 and 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/31/04</u> . | 6) <input type="checkbox"/> Other: _____ |

1/1

DETAILED ACTION

1. Claims 1-28 are currently pending.

Election/Restrictions

2. Applicant's election without traverse of Group I, claims 1-13, 18-21 and 26-28, phosphoethanolamine for species A, linolenate for species B, stigmasterol for species C, mammalian cell for species D and rice for species E in the reply filed on January 26, 2005 is acknowledged.
3. Claims 14-17 and 22-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 26, 2005.
4. Claims 1-13, 18-21, and 26-28 are examined on the merits.

Priority

5. Applicant's claim for priority is acknowledged. Applicant needs to correct the first page of the specification to correctly indicate how Application No. 09/302,953 is related to its parent cases. Specifically, that it is continuation, CIP, divisional, etc. of the applications to which priority is claimed. Also please note that applicant is attempting to claim priority to 09/070,807. According to USPTO records, this application number does not exist.

This current application is a CIP of 08/949,142, now US Pat. No. 6,103,529. The disclosure of this patent does not support using stigmasterol in the culture media. Thus, claims

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to this ingredient are only given a priority date to the filing date of 09/302,953 which is April 30, 1999.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-9, 12, 13, 18-21, and 26-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,103,529. Although the conflicting claims are not identical, they are not patentably distinct from each other because US '529 teaches a cell culture medium containing peptides, fatty acids, and lipids derived from plant sources which is the same culture medium that the present claims are drawn to. However, US '529 claims that the culture medium must be completely devoid of animal proteins which is not a limitation in the current claims. However, while the current claims encompass media that contain animal proteins, they are not a requirement. Therefore, the scope of the current claims overlaps with the claims of US '529.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 2, 7, 10, 11 and 28 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 98/24883 with the English abstract of JP 2000175643 providing inherent characteristics of stigmasterol.

As discussed above, claims drawn to stigmasterol ingredient are given a priority date to the filing date of 09/302,953 which is April 30, 1999.

WO '883 teaches an animal cell culture medium that contains stigmasterol (see page 5, line 31). The stigmasterol is combined with an animal cell culture medium (see page 10).

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WO '883 does not teach that the stigmasterol is from rice. JP '643 teaches that stigmasterol is a rice sterol. Thus, the stigmasterol in WO '883 is a sterol that is found in rice. Therefore, even if WO '883 does not disclose rice as the source of the stigmasterol, it still inherently is a rice sterol.

8. Claims 2, 7, 10, 11, 13, 20, 21, 26, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Iscove et al. (Journal of Experimental Medicine (1978) vol. 147, pp. 923-933) in light of CAPLUS abstract of Japanese Pat. No. 34002673 (April 1959).

The claims are drawn to an animal cell culture medium that contains a plant derived lipid or fatty acid.

Iscove teaches a culture medium for B lymphocytes that contains soybean lipids. The soybean lipid mixture contains sterols (see page 927, second paragraph). The lipids are mixed into an Eagle's animal cell culture medium (see last paragraph of page 923).

Iscove teaches that the lipid mixture contains sterols. However, the reference does not specifically teach that the sterol mixture contains stigmasterol. JP '673 teaches that soybean contains inherent contains the sterol stigmasterol. Thus, the culture medium of Iscove would inherently contain stigmasterol.

9. Claims 1, 6, 12, 18, 19, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Keay (Biotechnology and Bioengineering (1975), vol. 17, pp. 745-764).

The claims are drawn to an animal cell culture medium that contains a plant derived peptide.

Keay teaches that soy peptone can be used to culture animal cells (see page 750, Table II).

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10. Claims 1, 6, 12, 18, 19, 26, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. No. 5,741,705.

US '705 teaches an animal cell culture medium that contains rice proteins (see column 3, lines 45-46).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,741,705 and WO 98/24883.

As stated above, WO '883 teaches using the plant lipids stigmasterol in animal culture media. US '705 teaches using rice peptides in animal culture media. These references show that it was well known in the art at the time of the invention to use plant peptides and lipids animal

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culture media. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by US '705 and WO '883 that these two substances are used in animal culture media, an artisan of ordinary skill would have a reasonable expectation that a combination of the two substances would also be useful in creating an animal culture media. Therefore, the artisan would have been motivated to combine plant lipids and plant peptides into a single culture media. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

12. Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iscove in view of US Pat. No. 5,266,479.

As stated above, Iscove teaches a culture medium that contains soybean lipids. However, Iscove does not teach adding phosphoethanolamine to the medium. US '479 teaches that phosphoethanolamine is a growth supplement that can be added to animal cell culture media. Based on this teaching, a person of ordinary skill in the art would reasonably assume that this ingredient could beneficially be added to the culture medium taught by Iscove. Therefore, an artisan of ordinary skill would have been motivated to add phosphoethanolamine to the culture medium of Iscove.

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13. Claims 1 and 4 rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,741,705 in view of US Pat. No. 5,266,479.

As stated above, US '705 teaches using rice peptides to culture animal cells. However, US '705 does not teach adding phosphoethanolamine to the medium. US '479 teaches that phosphoethanolamine is a growth supplement that can be added to animal cell culture media. Based on this teaching, a person of ordinary skill in the art would reasonably assume that this ingredient could beneficially be added to the culture medium taught by US '705. Therefore, an artisan of ordinary skill would have been motivated to add phosphoethanolamine to the culture medium of US '705.

14. Claims 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keay in view of US Pat. No. 5,266,479.

As stated above, Keay teaches using soy peptone to culture animal cells. However, Keay does not teach adding phosphoethanolamine to the medium. US '479 teaches that phosphoethanolamine is a growth supplement that can be added to animal cell culture media. Based on this teaching, a person of ordinary skill in the art would reasonably assume that this ingredient could beneficially be added to the culture medium taught by Keay. Therefore, an artisan of ordinary skill would have been motivated to add phosphoethanolamine to the culture medium of Keay.

15. Claims 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/24883 in view of US Pat. No. 5,266,479.

As stated above, WO '883 teaches using stigmasterol in animal cell culture medium. However, WO '883 does not teach adding phosphoethanolamine to the medium. US '479

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teaches that phosphoethanolamine is a growth supplement that can be added to animal cell culture media. Based on this teaching, a person of ordinary skill in the art would reasonably assume that this ingredient could beneficially be added to the culture medium taught by WO '883. Therefore, an artisan of ordinary skill would have been motivated to add phosphoethanolamine to the culture medium of WO '883.

16. Claims 2, 7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keay in view of US Pat. No. 4,533,637.

As stated above, Keay teaches using soy peptone to culture animal cells. However, Keay does not teach adding linolenate (linolenic acid) to the medium. US '637 teaches that linolenate is an ingredient that can be added to animal cell culture media. Based on this teaching, a person of ordinary skill in the art would reasonably assume that this ingredient could beneficially be added to the culture medium taught by Keay. Therefore, an artisan of ordinary skill would have been motivated to add linolenate to the culture medium of Keay.

Please note that linolenate is a fatty acid that is found in rice (see English abstract of CN 1362507). Thus, even if the reference does not specifically teach this, linolenate is a rice fatty acid.

17. Claims 2, 7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keay in view of US Pat. No. 4,533,637.

As stated above, WO '883 teaches using stigmasterol in animal cell culture medium. However, WO '883 does not teach adding linolenate to the medium. US '479 teaches that linolenate is an ingredient that can be added to animal cell culture media. Based on this teaching, a person of ordinary skill in the art would reasonably assume that this ingredient could

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beneficially be added to the culture medium taught by WO '883. Therefore, an artisan of ordinary skill would have been motivated to add linolenate to the culture medium of WO '883.

Please note that linolenate is a fatty acid that is found in rice (see English abstract of CN 1362507). Thus, even if the reference does not specifically teach this, linolenate is a rice fatty acid.

18. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.

Susan D. Coe
4-11-05

Susan D. Coe
Primary Examiner
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